

**REMARKS**

Claims 1-11 are pending. By this Amendment, the specification and claims 1-10 are amended, Fig. 1 is corrected, and new Figs. 2-8 and claim 11 are added. No new matter has been added.

The specification is amended to include descriptions for new Figs. 2-8. Support for the amendments to the specification and new Figs. 2-8 is found in the originally filed claims and the following portions of the specification.

Specifically, support for new Fig. 2 and its description is found on at least page 6, lines 8-19 where a cavity of conical shape is disclosed, among others. Support for Fig. 3 and its description is found on at least page 6, lines 21-25 of the specification where a plurality of cavities distributed uniformly is disclosed, among others. Support for new Figs. 4-7 is found on at least page 3, lines 9-14, page 4, line 11-page 6, line 6, and page 10, lines 8-14 of the specification.

Specifically, on page 3, lines 9-14, it is stated that the transformation of the initial volume of the active principle and its streamlining at the moment of penetration into the skin are obtained by an effect of reversal and focusing. The reversal stated in the passage is the reversal of the blind cavity. This reversal of the blind cavity causes focusing of the active principle that is akin to the process described on page 4, line 11-page 6, line 6 of the specification.

That is, the active principle is formed into a central jet to permit injection through the epidermis. Figs. 4-7 show the formation of a central jet of the active principle. In addition, Figs. 4-7 show that the shock wave that propagates through the barrier not only violently ejects the active principle (page 4, lines 13-16), but also deform the barrier (page 10, lines 8-10). Therefore, Figs. 4-7 show the arrival of the shock wave, reversal of the barrier, and the

ejection and formation into a central jet of the active principle, which are fully supported in the cited passages of the specification as originally filed.

Finally, support for new Fig. 8 is found on at least page 13, lines 2-11 of the specification, where support for the three balls is located. Fig. 8 merely shows that there are three balls. No other information is implied.

Support for the amendments to claim 1 is found on at least page 3, lines 9-13, page 4, lines 11-20, and page 7, line 13. Support for the amendment to claim 4 is found in page 6, lines 17-19. Further, claims 1-10 are also amended in form to better comply with U.S. patent practice by deleting unnecessary reference numerals, and using "wherein".

Fig. 1 is corrected to show a second ball to harmonize the Figure with Fig. 8.

Applicants thank Examiners Thompson and Hayes for the courtesies extended to Applicants' representative during the December 16, 2003 personal interview. The points discussed are incorporated into the remarks below and constitute the Applicant's record of the interview.

Reconsideration is respectfully requested in view of the following.

**I. DRAWINGS**

On pages 2-4 of the Office Action, various drawing objections are made for alleged failure of the drawings to show specific features claimed or described in the specification.

Regarding the objection for failure to show three balls, Fig. 8 is added. Withdrawal of the objection is respectfully requested.

Regarding the alleged failure to show an inner groove, Applicants respectfully submit Fig. 1 does disclose an inner groove, not a protrusion because Fig. 1 shows the inner groove that is recessed in the walls of the trigger tube. The path of the groove on the back side of the trigger tube is shown as well. Withdrawal of the objection is respectfully requested.

Regarding the objection for failing to show an opening transverse section, Fig. 2 is added which shows, by a new reference number, the opening transverse section. The feature is supported in page 6, lines 8-11 and is supported in claim 4, and under MPEP §608.01(I), it is not new matter. Withdrawal of the objection is respectfully requested.

Regarding the objection concerning each blind cavity of claims 4 and 5, claims 4 and 5 are amended. Withdrawal of the objection is respectfully requested.

Regarding the plurality of cavities of claim 6, Fig. 3 is added. Withdrawal of the objection is respectfully requested.

Regarding the shock absorbing system of claim 10, Applicants respectfully submit that the feature is shown in Fig. 1 and also described on page 8, lines 23-27 of the specification. Withdrawal of the objection is respectfully requested.

## **II. REPLY TO REJECTIONS**

### **A. §112, Second Paragraph**

On page 4 of the Office Action, claims 1, 4, 5 and 6 are rejected under 35 U.S.C. §112, second paragraph for allegedly being indefinite.

Specifically, regarding claim 1, Applicants respectfully direct the Examiner's attention to page 4, lines 11-16 and page 4, lines 23-26 which describe the structure that allows for propagation of the shock wave. Further, page 5, lines 23-27 and page 7, lines 8-15 describe the characteristics of the structure that will allow for propagation of the shock wave and further describe what propagation of the shock wave entails. As the claims are read in light of the specification, the specification readily allows for one of ordinary skill in the art to ascertain what is meant by propagation of the shock wave.

Claim 4 is amended to clarify the claimed feature. Withdrawal of the rejection of claims 1, 4, 5 and 6 is respectfully requested.

**B. §102(b) Rejection**

On page 5 of the Office Action, claims 1-8 and 10 are rejected under 35 U.S.C. §102(b) over Figs. 1 and 2 of U.S. Patent No. 3,802,430 to Schwebel et al. (hereinafter "Schwebel I"), the figures of U.S. Patent No. 4,089,334 to Schwebel et al. (hereinafter "Schwebel II"), Figs. 1 and 2 of U.S. Patent No. 4,124,024 to Schwebel et al. (hereinafter "Schwebel III"), and Fig. 1 of WO 96/25190 to Bellhouse et al. (hereinafter "Bellhouse"). The rejections are respectfully traversed.

Applicants respectfully submit that Schwebel I, Schwebel II, Schwebel III and Bellhouse fail to disclose a needleless syringe comprising a propelling system including a shock wave generator device, a barrier comprising ... a downstream face ... having at least one blind cavity in which the active principle is accommodated ... wherein the barrier is fixed and the barrier ensures propagation of the shock wave through the barrier so that the shock wave is able to reverse the cavity to accelerate the active principle in the form of a central jet, as recited in claim 1.

Schwebel I and its subsequent improvements, Schwebels II and III, are directed to pyrotechnically powering an injector whereby a pyrotechnic charge creates gas that pushes a piston toward a barrel with an ampule containing medicament so that the medicament is discharged under high pressure. In Schwebel I, this is accomplished by pushing a piston 44 and a plug 18 into ampule 14 so that the medicament 15 is discharged through passages 19 and orifices 21 in a fine stream with a sufficiently high velocity to pierce the skin 45 (col. 3, lines 38-57).

In Schwebel II, the detonation of charge 23 by the primer 22 generates gas that bursts through the retainer 25, fills and builds up pressure within the chamber 21 and drives piston 18 toward the tip of an ampule 11 to discharge the medicament 17 through orifice 15 with

sufficient velocity to penetrate the skin and infuse the subcutaneous layer (col. 4, lines 25-34, Figs. 1-3).

In Schwebel III, the detonation of charge 36 produces gases that burst through retainer 37, fill and build up pressure within chamber 76, and drive plunger 52 into the tapered end 42 of the chamber. Under the thrust of plunger 52, the fluid charge 72 ruptures the scored membrane 70 and fills the foremost sections 46 and 48 of the chamber and the medicament 72 is discharged from the orifice 50 in a high velocity stream with sufficient force to penetrate the skin 78 (col. 4, lines 3-14, Fig. 1).

In Bellhouse, the release of helium from the reservoir 3 into the rupture chamber 4 depresses the plunger 16 whereupon the pressure in the chamber 5 is built up, causing membranes 9 to rupture, and releasing a flow of gas through the nozzle 7. As the gas flows through a narrow portion 12, the flow of gas is accelerated to supersonic speed of Mach 2 to Mach 8 and thereby, the particles are placed into the skin (page 7, lines 5-20). Bellhouse discusses a gaseous shock wave which travels through the passageway 10 and into a narrow portion 12. However, Bellhouse fails to disclose a plane shock wave that propagates through a barrier having an upstream face and a downstream face, the downstream face having at least one blind cavity, or a barrier that allows the shock wave to propagate through the barrier so that the shock wave is able to reverse the cavity to accelerate the active principle in the form of a central jet.

If fact, none of the applied references disclose a shock wave that is propagating through a barrier with an upstream face and a downstream face having at least one blind cavity. Further, none of the applied references disclose a shock wave that is able to reverse the cavity to accelerate the active principle in the form of a central jet. None of the applied references has structures that use the phenomenon of a shock wave that reverses the cavity.

During the December 16, 2003 personal interview, it was discussed whether Shcwebel I discloses the barrier as recited in claim 1. The Examiner indicated that her interpretation of the barrier was the ampule 14. According to the Examiner, the ampule 14 has a blind cavity, asserted to be the space enclosed within the ampule containing the medicament 15. The Examiner also indicated that the ampule 14 has an upstream face, i.e., the inner lining of the ampule located toward the plug 18 and a downstream face, i.e., the inner lining of the ampule 14 located toward the passages 19.

Such an interpretation is an unreasonably broad interpretation in view of the specification and disclosed in the drawing figures. Applicants respectfully note that such an interpretation was not stated in the September 10, 2003 Office Action.

Further, as disclosed on page 3, lines 26-page 4, line 1 of the specification, the barrier has two opposite faces, namely an upstream face, situated toward the shock wave generator, and another, the downstream face, situated toward the application guide. Taking this disclosure and Fig. 1, the description of upstream face and downstream face is clear, and the Examiner's interpretation of the ampule being equivalent to a barrier is unreasonable.

This is especially true when none of the applied references discloses that the barrier ensures propagation of the shock wave through the barrier and is able to reverse the cavity, as recited in claim 1, which means that the barrier has been deformed, as disclosed on page 10, lines 9-10. Such is not disclosed with regards to the ampule 14 in Schwebel I, and the other applied references.

Consequently, claim 1 is patentable over the applied references. Claims 2-8 and 10, which depend from claim 1, are likewise patentable over the applied references for at least the reasons discussed above and for the additional features they recite. Withdrawal of the rejection is respectfully requested.

**C.     §103(a) Rejection**

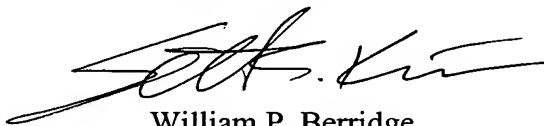
On page 5 of the Office Action, claim 9 is rejected under 35 U.S.C. §103(a) over Schwebel and Bellhouse. The Office Action fails to disclose exactly which Schwebel is being applied. Nevertheless, Applicants respectfully submit that none of Schwebels I, II and III nor Bellhouse disclose the features of claim 1 as discussed above from which claim 9 depends. Consequently, claim 9 is also patentable over the applied references for at least the reasons discussed above and for the additional features it recites. Withdrawal of the rejection of claim 9 is respectfully requested.

**III.   CONCLUSION**

For the reasons stated above, Applicants submit that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 1-10 are respectfully requested.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number set forth below.

Respectfully submitted,



William P. Berridge  
Registration No. 30,024

Seth S. Kim  
Registration No. 54,577

WPB/SSK:jcp

Attachments:  
Replacement Sheets

Date: January 6, 2004

**OLIFF & BERRIDGE, PLC**  
**P.O. Box 19928**  
**Alexandria, Virginia 22320**  
**Telephone: (703) 836-6400**

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